

MEDICARE PRESCRIPTION DRUG BENEFIT

MODEL GUIDELINES

DRUG CATEGORIES AND CLASSES IN PART D

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Medicare Prescription Drug Benefit
Summary of USP Approach and Methodology to the Model Guidelines

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The Model Guidelines that result from this Cooperative Agreement, as well as the assignment of any drug to any category or class is made only for the purpose of prescription drug coverage under Part D and does not affect other activities.

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INTRODUCTION

Medicare Modernization Act

On December 8, 2003, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Medicare Modernization Act or MMA) was enacted into law. This new law is one of the most significant changes to Medicare since its inception. The MMA establishes a new voluntary outpatient prescription drug benefit program. The addition of outpatient prescription drugs to the Medicare program reflects Congress' recognition of the fundamental change in recent years on how medical care is delivered in the United States and recognizes the vital role of prescription drugs in our health care delivery system. This new benefit will become available to beneficiaries beginning on January 1, 2006.

Beneficiary Protection

Under the MMA, there are provisions to protect the beneficiary. These provisions relate to how Plan Sponsors develop and design plans and offer them to beneficiaries. A Plan Sponsor (Plan) will work in ways that promote access and quality healthcare yet also control costs effectively.

- **USP's Role:** The United States Pharmacopeia's (USP) role in this new prescription drug benefit program falls under the beneficiary protection provisions of the MMA. The law specifically requires the Secretary of the Department of Health and Human Services (the Secretary) to request that USP develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes (USP Model Guidelines) that may be used by prescription drug plans in developing their formularies. USP is also to revise such classification from time to time to reflect changes in therapeutic uses of covered drugs and additions of new covered drugs.

The Centers for Medicare and Medicaid Services (CMS) has been charged with the responsibility for overseeing the implementation of the new prescription drug benefit. Under the statute, if a Plan designs the drug categories and classes within their formulary in a way that is consistent with the USP Model Guidelines, then CMS must find that the design does not substantially discourage enrollment by beneficiaries.

The Model Guidelines Expert Committee

To develop the Model Guidelines, USP created a Model Guidelines Expert Committee (Expert Committee). The mission of the Expert Committee is to fulfill the intent of Congress by creating a list of categories and classes that protects Medicare beneficiaries' access to the drugs they need and supports the United States Government's efforts to successfully implement the Medicare prescription drug benefit. A primary motivation for the Expert Committee relates to three goals:

- 1) Assure beneficiary access to the drugs they need, preventing substantial discouragement from enrollment;
- 2) Produce Model Guidelines that offer clear and relevant categories and classes, and that will provide some consistency in the formulary structures of Prescription Drug Plans (PDPs);
- 3) Assist CMS in its evaluations of drug plan formularies.

The Expert Committee sought input from numerous sources, including four Advisory Forums, an environmental scan, USP's standing information Expert Committees, public comments, and other sources of information. The insights gathered addressed common formulary and prescribing practices as well as issues specific to the Medicare population. The Expert Committee created a draft of the Model Guidelines (August 2004) to solicit targeted and specific public comment and then submitted a revised draft of the Model Guidelines to CMS on December 10, 2004 based on an evaluation of the feedback received. The final deliverable (herein) was completed after review and consideration of CMS comments to the revised draft – received on December 20, 2004.

Overview of the Model Guidelines

USP's Model Guidelines consist of a listing of therapeutic categories (first column of the Model Guidelines) and associated pharmacologic classes (second column of the Model Guidelines) that create a framework that PDPs and their pharmacy and therapeutics (P&T) committees, if needed, may follow as they create a drug plan formulary. For a detailed discussion of how the Model Guidelines were developed, please refer to the companion document entitled *Medicare Prescription Drug Benefit – Summary of USP Approach and Methodology to the Model Guidelines*.

The USP Model Guidelines are not intended to serve as treatment guidelines, but to provide a non-discriminatory classification system for the structure of a Plan's formulary.¹ The practice and responsibility for prescribing specific medications for particular indications should remain with practitioners. Practitioners and Plans are encouraged to continue to work together to assure appropriate drug therapy that is consistent with current practice and should not be constrained by the association of a particular class with a particular category within the Model Guidelines. For example, whereas Beta Blockers are a class associated with the Cardiovascular Agents category, these medications are often used for other indications as well.

The USP Model Guidelines represent the only classification system specifically developed for the Medicare Prescription Drug Benefit. The Model Guidelines were developed in a way that provides Plans with a flexible, science-based standard that supports the interests of practitioners and patients for comprehensive pharmaceutical care. While Plans are not required by law to use the Model Guidelines, the use of a standardized structure for the many formularies that will emerge and evolve for the Part D benefit will be especially valuable in making the benefit clear and comprehensive for all constituencies.

¹ Note: The Model Guidelines are not a formulary, but instead a listing of categories and classes.

As set forth in the MMA Proposed Rule (published on August 3, 2004), if a Plan chooses to follow the USP Model Guidelines, at least two drugs will be required in each category or class (unless only one drug exists). If two drugs are contained in the class, it meets the two drug requirement for the category associated with that specific class. Where there is no pharmacologic class associated with a therapeutic category, a Plan would need to provide two drugs in the category to meet this requirement.

While the Model Guidelines are an important tool that will help Plans and CMS in the implementation of the benefit, the formulary classification system is only the first step of a comprehensive formulary review process by CMS – as described in the CMS Draft Guidance issued on December 3, 2004. In addition to establishing the categories and classes of the Model Guidelines, the Expert Committee also created a separate listing of formulary key drug types to assist CMS in this formulary review process. The purpose of this listing is to provide additional guidance to CMS regarding drug types that the Expert Committee believed CMS should look for in Plans' formularies. By checking a Plan's formulary for at least one item in each of the formulary key drug types – and requesting justification if a formulary excludes any of these items – CMS can help ensure that a formulary is comprehensive and will not substantially discourage enrollment of eligible beneficiaries. For a review of the formulary key drug type listings, please see the document entitled *USP Comments to the Draft Guidance – CMS Formulary Review for the Medicare Prescription Drug Benefit*.

USP MODEL GUIDELINES

The following pages offer the USP Model Guidelines (Columns 1 and 2) and a column entitled Notes. The Notes have been added to provide additional information and clarification regarding certain categories and classes. Recognizing that the Model Guidelines will be dynamic, the USP Model Guidelines Expert Committee will revise the therapeutic categories and pharmacologic classes over time to accommodate new information (e.g., regarding drug safety), changes in therapeutic uses of covered drugs, and approvals of new Part D drugs.

MODEL GUIDELINES			NOTES
No.	THERAPEUTIC CATEGORY	PHARMACOLOGIC CLASS	ADDITIONAL INFORMATION
1	Analgesics	Opioid Analgesics	See Antimigraine Agents Therapeutic Category for similar/related therapies
2		Non-opioid Analgesics	See Anti-inflammatories Therapeutic Category for similar/related therapies
3	Anesthetics		
4	Antibacterials	Beta-lactam, Cephalosporins	
5		Beta-lactam, Penicillins	
6		Beta-lactam, Other	Includes drugs such as Loracarbef
7		Macrolides	
8		Quinolones	
9		Sulfonamides	
10		Tetracyclines	
11		Antibacterials, Other	Includes drugs such as Trimethoprim, Vancomycin, Lincomycin, Clindamycin, Furazolidone, Nitrofurantoin, Linezolid, Bacitracin, Chloramphenicol, Daptomycin, Fosfomycin, Methenamine, Metronidazole, Mupirocin, Rifaximin, Spectinomycin
12	Anticonvulsants	Calcium Channel Modifying Agents	
13		Gamma-aminobutyric Acid (GABA) Augmenting Agents	
14		Glutamate Reducing Agents	
15		Sodium Channel Inhibitors	
16	Antidementia Agents	Cholinesterase Inhibitors	
17		Glutamate Pathway Modifiers	
18		Antidementia Agents, Other	Includes drugs such as Ergoloid Mesylates

MODEL GUIDELINES			NOTES
No.	THERAPEUTIC CATEGORY	PHARMACOLOGIC CLASS	ADDITIONAL INFORMATION
19	Antidepressants	Monoamine Oxidase (Type A) Inhibitors	
20		Reuptake Inhibitors	
21		Antidepressants, Other	Includes drugs such as Bupropion, Maprotiline, Mirtazapine, Trazodone
22	Antiemetics		
23	Antifungals		
24	Antigout Agents		
25	Anti-inflammatories	Glucocorticoids	See Adrenal Pharmacologic Class for similar/related therapies
26		Nonsteroidal Anti-inflammatory Drugs	See Non-opioid Analgesics Pharmacologic Class for similar/related therapies
27	Antimigraine Agents	Abortive	See Analgesics Therapeutic Category for similar/related therapies
28		Prophylactic	See Autonomic Agents and Cardiovascular Agents Therapeutic Categories for similar/related therapies
29	Antimycobacterials	Antituberculars	
30		Antimycobacterials, Other	Includes drugs such as Clofazimine, Dapsone, Rifabutin
31	Antineoplastics	Alkylating Agents	
32		Antimetabolites	
33		Immune Modulators and Vaccines	
34		Molecular Target Inhibitors	
35		Nucleoside Analogues	
36		Protective Agents	
37		Topoisomerase Inhibitors	
38		Antineoplastics, Other	Includes drugs such as Carboplatin, Cisplatin, Oxaliplatin

MODEL GUIDELINES			NOTES
No.	THERAPEUTIC CATEGORY	PHARMACOLOGIC CLASS	ADDITIONAL INFORMATION
39	Antiparasitics	Anthelmintics	
40		Antiprotozoals	
41		Pediculicides/Scabicides	
42	Antiparkinson Agents	Catechol <i>O</i> -methyltransferase (COMT) Inhibitors	
43		Dopamine Agonists	
44		Antiparkinson Agents, Other	Includes drugs such as Bzotropine, Biperidin, Bromocriptine, Diphenhydramine, Procyclidine, Selegiline, Trihexyphenidyl
45	Antipsychotics	Non-phenothiazines	
46		Non-phenothiazines/Atypicals	
47		Phenothiazines	
48	Antivirals	Anti-cytomegalovirus (CMV) Agents	
49		Antiherpetic Agents	
50		Anti-human immunodeficiency virus (HIV) Agents, Fusion Inhibitors	
51		Anti-HIV Agents, Non-nucleoside Reverse Transcriptase Inhibitors	
52		Anti-HIV Agents, Nucleoside and Nucleotide Reverse Transcriptase Inhibitors	
53		Anti-HIV Agents, Protease Inhibitors	
54		Anti-influenza Agents	
55		Antivirals, Other	Includes drugs such as Adefovir and Ribavirin
56	Anxiolytics	Antidepressants	
57		Anxiolytics, Other	Includes drugs such as Buspirone and Meprobamate

MODEL GUIDELINES			NOTES
No.	THERAPEUTIC CATEGORY	PHARMACOLOGIC CLASS	ADDITIONAL INFORMATION
58	Autonomic Agents	Parasympatholytics	
59		Parasympathomimetics	
60		Sympatholytics	See Cardiovascular Agents and Genitourinary Agents Therapeutic Categories for similar/related therapies
61		Sympathomimetics	See Cardiovascular Agents Therapeutic Category for similar/related therapies
62	Bipolar Agents		
63	Blood Glucose Regulators	Antihypoglycemics	
64		Hypoglycemics, Oral	
65		Insulins	
66	Blood Products/Modifiers/Volume Expanders	Anticoagulants	
67		Blood Formation Products	
68		Coagulants	
69		Platelet Aggregation Inhibitors	
70	Cardiovascular Agents	Alpha-adrenergic Agonists	See Autonomic Agents Therapeutic Category for similar/related therapies
71		Alpha-adrenergic Blocking Agents	See Autonomic Agents Therapeutic Category for similar/related therapies
72		Antiarrhythmics	
73		Beta-adrenergic Blocking Agents	
74		Calcium Channel Blocking Agents	
75		Direct Cardiac Inotropics	
76		Diuretics	
77		Dyslipidemics	
78		Renin-angiotensin-aldosterone System Inhibitors	

MODEL GUIDELINES			NOTES
No.	THERAPEUTIC CATEGORY	PHARMACOLOGIC CLASS	ADDITIONAL INFORMATION
79		Vasodilators	
80	Central Nervous System Agents	Amphetamines	
81		Non-amphetamines	
82	Dental and Oral Agents		
83	Dermatological Agents	Dermatological Anesthetics	
84		Dermatological Antibacterials	
85		Dermatological Antifungals	
86		Dermatological Anti-inflammatory	
87		Dermatological Antipruritic Agents	
88		Dermatological Antivirals	
89		Dermatological Keratolytics	
90		Dermatological Mitotic Inhibitors	
91		Dermatological Photochemotherapy Agents	
92		Dermatological Retinoids	
93		Dermatological Tar Derivatives	
94		Dermatological Vitamin D Analogs	
95		Dermatological Wound Care Agents	
96	Deterrents/Replacements	Alcohol Deterrents	
97	Enzyme Replacements/Modifiers		
98	Gastrointestinal Agents	Antispasmodics, Gastrointestinal	
99		Histamine ₂ (H ₂) Blocking Agents	

MODEL GUIDELINES			NOTES
No.	THERAPEUTIC CATEGORY	PHARMACOLOGIC CLASS	ADDITIONAL INFORMATION
100		Irritable Bowel Syndrome Agents	
101		Protectants	
102		Proton Pump Inhibitors	
103		Gastrointestinal Agents, Other	Includes drugs such as Sevelamer, Ursodiol
104	Genitourinary Agents	Antispasmodics, Urinary	
105		Benign Prostatic Hypertrophy Agents	See Autonomic Agents and Cardiovascular Agents Therapeutic Categories for similar/related therapies
106		Impotence Agents	
107		Prostaglandins	See Hormonal Agents, Stimulant/Replacement/Modifying Therapeutic Category for similar/related therapies
108	Hormonal Agents, Stimulant/Replacement/Modifying	Adrenal	See Anti-inflammatories Therapeutic Category for similar/related therapies
109		Parathyroid/Metabolic Bone Disease Agents	
110		Pituitary	
111		Prostaglandins	See Genitourinary Agents Therapeutic Category for similar/related therapies
112		Sex Hormones/Modifiers	
113		Thyroid	
114	Hormonal Agents, Suppressant	Adrenal	
115		Pituitary	
116		Sex Hormones/Modifiers	
117		Thyroid	
118	Immunological Agents	Immune Stimulants	
119		Immune Suppressants	

MODEL GUIDELINES			NOTES
No.	THERAPEUTIC CATEGORY	PHARMACOLOGIC CLASS	ADDITIONAL INFORMATION
120		Immunomodulators	
121	Inflammatory Bowel Disease Agents	Glucocorticoids	See Hormonal Agents, Stimulant/Replacement/Modifying Therapeutic Category for similar/related therapies
122		Salicylates	
123		Sulfonamides	See Antibacterials Therapeutic Category for similar/related therapies
124	Ophthalmic Agents	Ophthalmic Anti-allergy Agents	
125		Ophthalmic Antibacterials	
126		Ophthalmic Antifungals	
127		Ophthalmic Antiglaucoma Agents	
128		Ophthalmic Anti-inflammatories	
129		Ophthalmic Antivirals	
130		Ophthalmics, Other	Includes drugs such as Formivirsen
131	Otic Agents	Otic Antibacterials	
132		Otic Anti-inflammatories	
133	Respiratory Tract Agents	Antihistamines	
134		Antileukotrienes	
135		Bronchodilators, Anticholinergic	
136		Bronchodilators, Anti-inflammatories	
137		Bronchodilators, Phosphodiesterase 2 Inhibitors (Xanthines)	
138		Bronchodilators, Sympathomimetic	
139		Mast Cell Stabilizers	
140		Mucolytics	

MODEL GUIDELINES			NOTES
No.	THERAPEUTIC CATEGORY	PHARMACOLOGIC CLASS	ADDITIONAL INFORMATION
141		Respiratory Tract Agents, Other	Includes drugs such as Alpha-1-proteinase Inhibitor, Human; Benzonatate; Guaifenesin; Iodinated Glycerol; Potassium Iodide; Tetrahydrozoline
142	Sedatives/Hypnotics		
143	Skeletal Muscle Relaxants		
144	Therapeutic Nutrients/Minerals/Electrolytes	Electrolytes/Minerals	
145		Vitamins	All others except prenatal vitamins excluded from coverage
146	Toxicologic Agents	Opioid Antagonists	

SUMMARY

The USP Final Draft Model Guidelines contains the following totals:

- 41 therapeutic categories
 - 32 with associated drug classes
 - 9 with no associated drug classes
- 137 pharmacologic classes
- 146 unique therapeutic categories and pharmacologic classes.

This total of 146 (as opposed to 178, the total sum of categories and classes) results from analysis of the pharmacologic class column. Adding the 137 classes to the 9 categories with no associated drug classes yields 146 total categories and classes.